REMARKS

Claims 1-26 and 31-55 are pending in this application. Claims 1, 5, and 55 have been amended. Support for the amendments can be found throughout the specification and specifically, for example, at p. 29 lines 12 – p. 30 line 19 of the. No new matter is believed to be added by way of this amendment. The rejection of independent claims 1 and 55 as well as the claims dependent therefrom is believed to be moot in light of this amendment.

The Applicants acknowledge with appreciation the allowance of claims 31-38 as well as the indication that claims 7-19, 21-23, 45-46 and 52-53 would be allowable if rewritten in independent form including all of the limitations of the base clams and any intervening claims.

Claim Rejections Under 35 U.S.C. §102

A determination of anticipation under 35 U.S.C. §102 requires a finding that each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. Furthermore, the identical invention must be shown in as complete detail as is contained in the claim. MPEP §2131.

Claims 1-6, 20, 24-26, 39-43, 47-50, and 54-55 were rejected under 35 U.S.C. §102(b) as being anticipated by Sander et al. (U.S. Patent No. 5,374,268). Applicants respectfully disagree and reconsideration and withdrawal of this rejection is requested.

Independent Claim 1:

Applicants respectfully submit that it is unreasonable to read the barbed anchor members of Sander onto Applicants claims to a tissue connector assembly comprising clips. Sander's anchor members (14) are not clips. The anchor members of Sander are anchoring members "which are constructed of a bioresorbable material" Col. 3 lines 48- 49. The anchor members of Sander "essentially comprise absorbable rods having outwardly projecting barbs…the barbs are provided to anchor the device in the tissue." Col. 2 lines 21-23; Col. 2 lines 39-40. Applicants have amended claim 1 to now include "wherein at least one of said two clips is a self-closing clip." which was previously included in claim 5 of the present application. In the rejection of previous claim 5, the Examiner sets forth, "in Sander's reference both clips are self closing when

they are inserted in the tissue". However, nowhere in the disclosure of Sander is there indication or reference to the anchor members of Sander having the ability to close, much less to self-close. Sander discloses a flexible or suture member and that the "flexible material allows for movement of anchoring members *with respect to one another*." (Col. 3 lines 47-58). Thus, the anchor members of Sander are disclosed as moving only with respect to one another, and not, as Applicants claim, movable individually upon themselves with the ability to self-close.

In addition claims 2, 4-6 and 39-40 which depend from claim 1 contain additional allowable subject matter. With regard to claim 5, as discussed above regarding claim 1, the anchor members of Sander are movable only with respect to one another and do not move upon themselves and therefore do not disclose having open or closed configurations as provided in amended claim 5. Furthermore, Sander does not disclose anchor members with the ability to assume a configuration whereby the end point of an individual anchor member is movable with respect to the other end point of that same anchor member thereby causing a reduction in the distance between anchor member end points. Therefore Sander's anchor members are not clips having open and closed configurations as amended claim 5 sets forth.

With regard to claim 6, the Examiner advanced "the bridge portion is flexible and there for has shape memory material". Applicants respectfully submit that the conclusion drawn by the Examiner that an element which is flexible therefore has shape memory characteristics is unreasonable and contrary to that which is well known in the art regarding shape memory materials. A shape memory alloy has specific characteristics beyond the ability to flex and may for example exhibit pseudoelastic (e.g. superelastic) behavior when deformed at a temperature slightly above its transformation temperature (See generally Applicants' Specification and specifically at p.13 line 30 – page 14 line 23). Sander does not disclose the suture or flexible member as being made of a shape memory material, rather, the anchor members of Sander are disclosed as being made of "a bioresorbable material, such as homopolymers and copolymers." Col. 3 lines 48-49.

With regard to claim 39, Sander does not disclose clips having memory set loop configurations or deformed configurations. The barbed anchor members of Sander are made of absorbable material and are anchored into tissue. There is no suggestion of a memory set configuration of Sander's anchor members since the anchor members are not made of a shape

memory material as discussed above. Furthermore, as discussed above with respect to the open and closed configurations of Applicants' invention, the anchor members of Sander are likewise not deformed into loop configurations. Since Sander fails to disclose the tissue connector assembly of the present invention, withdrawal of the rejection of claim 1 and the claims which depend therefrom as being anticipated by Sander is respectfully requested.

Independent Claim 20:

The discussion provided above with respect to claim 1 and the claims dependent therefrom applies with equal force to claim 20. Claim 20 provides at least one self-closing clip having an open configuration and a closed configuration. As discussed, Sander does not disclose a self-closing clip nor does Sander disclose a clip having open and closed configurations. Furthermore, claim 20 provides "wherein the open configuration is a biased configuration and the closed configuration is an unbiased configuration". Sander's anchor members are not biased in an open configuration. The Sander disclosure includes no mention of a biased member nor is there a reason to provide such a member. The Examiner directs attention to Figures 1 and 4 for the proposition that Sander's anchor members are biased in an open configuration. However, as discussed in detail with regard to claim 1 above, the anchor members are joined by a flexible suture which has no biasing capability and which allows only for movement of the anchor members with respect to one another. The Examiner has not provided support from the disclosure of Sander for the notion that the barbed anchor members of Sander are biased in an open configuration. The Examiner directs attention to Col. 3 lines 50-60 of Sander. This portion of the disclosure of Sander provides only that "the anchoring members are formed of a copolymer of lactide and glycolide". Movement of the anchor members as disclosed in the figures and the specification is only to the extent that the barbed anchor members can move closer in proximity to *one another* and not, as Applicants' disclose, upon themselves from biased open configuration.

In addition, claim 20 discloses "a release mechanism having a first position to bias said self-closing clip in said open configuration, and a second position to unbias said self-closing clip into said closed configuration." The Examiner asserts that "the bridge portion is also defined as a release mechanism" but provides no support for this proposition. Indeed, the so-called bridge

portion of Sander is not disclosed as a release mechanism. Even assuming arguendo that Sander's bridge portion was disclosed as having a release mechanism, the barbed anchor members to which the so-called bridge portion is attached are not biased in an open configuration and release of the anchor members via a release mechanism would serve only to detach the anchor members from the suture material and would not result in an anchor member assuming a closed configuration. For at least these reasons, Sander fails to disclose the tissue connector assembly of claim 20 and withdrawal of the rejection of the claims as being anticipated by Sander is respectfully requested.

Independent Claim 24:

Independent claim 24 discloses in part a self-locking clip. The Examiner contends that "in Sander's reference both clips are self closing when they are inserted in the tissue". As discussed above, the clips of Sander are not self closing. Likewise, the anchor members of Sander are not self locking and Sander lacks any disclosure that the anchor members have the ability to self-lock. Applicants respectfully request that the Examiner specifically point out where in the disclosure of Sander there exists the ability of any member of Sander to self close or self-lock and how this would be carried out. Claims 25 and 26 which depend from claim 24 are allowable for the reasons provided herein as well as for containing additional allowable subject matter. For example, Claim 25 discloses "a release mechanism, wherein said release mechanism activates said release of said two piercing members from said respective two ends." and claim 26 provides in part "said release mechanism activates the closing of said self-closing clip." As discussed above with respect to claim 20, Sander does not disclose such a release mechanism. For these reasons, independent claim 24 and the claims which depend therefrom are allowable and withdrawal of the rejection of the claims as being anticipated by Sander is respectfully requested.

Independent Claim 41:

Independent Claim 41 provides:

> Tissue connector apparatus comprising an elongated member having a first loop shaped portion adapted to hold tissue therein, a second loop shaped portion adapted to hold

tissue therein, and a bridge portion bridging said first and second loop shaped portions, each loop shaped portion having a free end and being deformable into a second deformed shape where it tends to return towards its loop shape.

The Examiner points to Figure 2 of Sander in support of the notion that Sander discloses the loop shaped portions of claim 41. The Examiner does not specifically point to which member of Sander has the supposed loop shape portions. Assuming arguendo that the Examiner is pointing to the curved needle members (32) of Sander, the curved needles of Sander do not tend to return toward a loop shape as does the elongated member disclosed in Applicants' claim. The needles of Sander are "preferably constructed of stainless steel or other surgical metal alloy, having a sharp tip at one end to facilitate penetration through tissue". Col. 3 lines 39-41. Thus, the needles are constructed of rigid materials and as such have no ability to return to a predetermined configuration. Claims 43, 44, and 47 depend from claim 42 contain additional allowable subject matter and are allowable at least by reason of their dependency upon an allowable independent claim. For these reasons, independent claim 42 and the claims which depend therefrom are allowable and withdrawal of the rejection of the claims as being anticipated by Sander is respectfully requested.

Independent Claim 48:

Claim 48 provides in part, "each loop shaped portion being deformable into a second deformed shape and having the property of tending to return towards its loop shape." As discussed with regard to Claim 42, immediately above, the property of tending to return toward a loop shape is not present in the Sander reference. Sander is devoid of any disclosure of a member having the properties of being deformable yet retaining the tendency to return toward a loop shape. The Examiner cites as support for this notion, Figures 1 and 4 of Sander. As discussed extensively above, Figures 1 and 4 disclose bioabsorbable barbed anchor members being secured to needles at a joint. Even if the Examiner intends that the needles of Sander be read onto the loop shaped portions of the elongated members of Applicants claims, the property of tending to return toward a loop shape remains undisclosed in Sander. Since Sander fails to disclose every element found in claim 48 and the claims dependent therefrom (Claims 49, 50 and 54), independent claim 48 and the claims which depend therefrom are allowable and rejection of the claims as being anticipated by Sander is respectfully requested.

Claim Rejections Under 35 U.S.C. §103

Claims 44 and 51 were rejected under 35 U.S.C. §103(a) as being unpatentable over Sander et al. (U.S. patent No. 5,374,268). Applicant requests reconsideration and withdrawal of this rejection.

First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, the art must provide a reasonable expectation of success. Third, the prior art reference must teach or suggest all the claim limitations. MPEP § 2143. In addition, rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness. *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727. Also, in the Examination Guidelines for Determining Obviousness in view of the KSR decision, the USPTO has noted that the key to supporting any rejection under §103 is the *clear articulation of the reasons(s)* why the claimed invention would have been obvious. Indeed, the Supreme Court in KSR noted that the analysis supporting a rejection under 35 U.S.C. §103 *should be made explicit*. Thus, it remains necessary to identify some reason that would have led a person of ordinary skill in the art to modify the teachings of a reference in a particular manner in order to establish prima facie obviousness.

Applicants respectfully submit that the Examiner has neither articulated nor made explicit either reasons or factors which would have led a person of ordinary skill in the art to modify Sander to provide a wire made of nitinol. The examiner posits that "it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Sander's invention by providing a wire that is made from nitinol in order to make it safer for the patient, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice." However, if Sander were to be modified to provide a wire made of nitinol, there is no reasonable expectation that the Sander device would work successfully for its intended purpose. To the contrary, Sander teaches away from the configuration of Applicants' claims 44 and 51. "A *prima facie* case of obviousness may also be rebutted by showing that the art, in any material

respect, teaches away from the claimed invention." MPEP §2144.05. The intended purpose of Sander as a resorbable tissue repair device, if modified as suggested by the Examiner, would be destroyed since substitution of nitinol would render the device non-resorbable. The intended use of the Sander device is as a tissue repair device which "facilitates healing of the torn muscle tissue by providing a *completely resorbable* suture-like device which may be accurately placed across the tear and which may remain in place *until the tear is completely healed*." Col. 2 lines 14-17, emphasis added. The Federal Circuit has consistently held that when a §103 rejection is based upon a modification of a reference that destroys the intent, purpose, or function of the invention disclosed in the reference, such a proposed modification is not proper and the prima facie case of obviousness cannot be properly made. *See* e.g. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984).

Furthermore, Applicants respectfully submit that the Examiner has not suggested how, nor does Sander disclose that constructing the anchor members or suture of Sander out of anything other than a bioresorbable material would make the device of Sander safer. Sander discloses that "the material compositions of the suture and anchoring means are selected to provide the desired resorption rate to allow sufficient time for healing." Col. 2 lines 62-65. Therefore, if the modification suggested by the Examiner were to be carried out, the suture and anchor members of Sander, which are intended to be left in the tissue, would no longer be resorbable and would thus *compromise* rather than improve the safety of the patient. Accordingly, neither the knowledge available to those skilled in the art, nor the references themselves suggest modifying Sander's device to include wires made of nitinol.

If the Examiner maintains any of the foregoing rejections, Applicants request that the Examiner clearly point to specific examples in the cited references that support any rejection so maintained.

Applicants submit that the pending claims are now in condition for allowance and respectfully requests the issuance of a formal Notice of Allowance at an early date. If a telephone interview would advance prosecution of the application, the Examiner is invited to telephone the undersigned at the number provided below.

Respectfully submitted,

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